

Final Statement of Reasons

Subject Matter of Proposed Regulations: Notice to Consumers

Section Affected: Amend Title 16, Section 1707.2

Hearing Date: April 25, 2002

Updated Information:

The proposed amendment to the board's Notice to Consumers was adopted by the board during the regulation hearing as initially noticed in March and April 2002.

However, two technical, nonsubstantive changes were made to the noticed language to correct typographical errors. These specific changes are indicated below in double strikeout or underscore:

1. 1707.2(c) When oral consultation is provided, it shall include at ~~least~~ least the following:
2. 1707.2(f) What foods, drinks or activities . . .

Summary of Comments Received During the 45-Day Comment Period (March 8 through April 22, 2002)

1. In a letter dated April 19, 2002, and faxed to the board, Joan B. Lee, legislative liaison for the Gray Panthers California, made several comments in support of the proposal.

Ms. Lee urges that the poster be available at least in English and Spanish, and encourages a means for patients to get the information in Chinese and other languages.

The board plans to produce the posters in English, Spanish, Chinese and one other language. The board also intends to produce miniature versions of the poster in these languages as well as others so that this information will be available to patients in pharmacies, via provisions of camera-ready, translated text that can be downloaded from the board's website.

The Gray Panthers request that a large poster be produced by the board, and that the poster be readily displayed and visible to patients in the pharmacy, near where prescriptions are turned in.

Although not part of the regulation's language per se, these comments are consistent with board actions planned to produce the poster. The final poster will be 17 x 22 inches in size, which is a reasonably large poster. The content will be

focused to highlight the five questions over all other text, so that the questions are readily visible from a distance in the pharmacy. However, because of the diversity of structural configurations in California pharmacies, the board will not require that the poster be displayed in a specific location other than as required in the first sentence of 1707.2(f) that the poster be: “prominently posted in a place conspicuous to and readable by prescription drug consumers . . . “

Placement of the poster in pharmacies and compliance with the “readable by prescription drug consumers” provision will be a component of board inspections throughout California.

The Gray Panthers also support the inclusion of an 800 number on the poster as well as a means for patients to call somewhere for medication information if they are not counseled.

The board plans on obtaining an 800 number and placing this on the poster as well as listing the board’s address and website. This will aid consumers with inquiries or complaints about pharmacies. Consumers who are not counseled as required by law will be asked to submit a complaint. They also will be advised to contact a pharmacist to obtain drug information immediately so that lack of this information does not interrupt their drug therapy.

2. John Cronin, senior vice president of the California Pharmacists Association (CPhA), submitted comments on behalf his organization in support of the regulation and urging the board to adopt the language as noticed.

Dr. Cronin states that the changes to the Notice to Consumers are long overdue, and will provide consumers with “useful guidance regarding the information they should be seeking about their prescription medications.” The new notice will serve both consumers and pharmacists in improving the quality of dialogue of discussions regarding prescription medication.

Summary of Comments Received During the Public Hearing on April 25, 2002:

The board received comments from one individual during the hearing.

Joseph Partansky provided oral comments in support of the regulation. He stressed the need for the poster, and recommended that the board include an 800 number, which he stated was required as an ADA accommodation. In support of this statement, he provided the board with a booklet titled: “Americans with Disabilities Act – ADA a Comprehensive Overview,” published by the California Department of Rehabilitation (included under Tab G “Written Comments Received during Hearing”).

On page 29 of this booklet is the following quotation:

Public agencies are also required to ensure that their communications with persons with disabilities are as effective as their communications with others. To meet this obligation, governmental agencies must make available appropriate auxiliary aids and services, such as qualified interpreters, note takers, handset amplifiers, telecommunications devices for people who are deaf (TTYs), readers, Braille and large-print materials. Telecommunication relay services may be used by public agencies to communicate with people who are deaf, hard of hearing or speech impaired.

The board will place an 800 number on the poster to facilitate communication of consumers with the board. Should individuals with hearing or speaking disabilities need to reach the board, they will be able, as will any other consumer, to reach the board through the 800 number via connection with a TTY or other specialized service.

Mr. Partansky also encouraged the board to produce the poster in different languages, but specifically requested to have it printed in English and Spanish. He encouraged the board to allow individuals to translate the poster into diverse languages.

The board will produce the posters in English, Spanish, Chinese and one other language. Additionally the board will produce camera-ready versions of brochure-size posters in additional languages. These camera-ready brochures will be available to pharmacies to photocopy for distribution to their patients in a greater diversity of languages.

Mr. Partansky requested that the board require that the posters be placed in pharmacies on the cash registers or near the point of sale.

The board declines to specify a specific location in a pharmacy to display the posters. The posters will be a rather large size (17 x 22 inches), too large to be placed on a cash register. The layout will feature the five questions patients should understand before taking prescription medications so that the questions should be visible from a distance in the pharmacy. However, because of the diversity of structural configurations in California pharmacies, the board will not require that the poster be displayed in a specific location other than as required in the first sentence of 1707.2(f) that the poster be: “prominently posted in a place conspicuous to and readable by prescription drug consumers . . . “

Board inspections will include monitoring a pharmacy’s compliance with the posting requirement in an area readily readable by the public.

Mr. Partansky suggested that the board’s website be printed on the poster.

The board plans to include its website address on the poster.

Mr. Partansky stated that the board should not allow any exemption to pharmacists not to consult patients. Consequently, the exemption in section 1707.2(b)(3) should be altered to require pharmacists to consult patients in inpatient settings in hospitals and inmates in correctional facilities.

The board does not propose to modify its patient consultation requirements for pharmacists in this rulemaking. It could be argued that such a modification is outside the notice provisions of the board's initial notice and statement of reasons for the rulemaking. Moreover, the board does not at this time intend to require pharmacist consultation of patients in hospitals or of inmates where others control the administration of medications to the patients to inmates. Patient consultation by pharmacists is required in outpatient settings or upon discharge of patients from hospitals, where the patient will be responsible for taking his or her own medications. In inpatient settings or in correctional facilities, other health care professionals administer medications to patients, typically in unit doses. Patient knowledge and understanding of how to take medications in inpatient settings, while important, is not as critical when other health care professionals are responsible for administering the medication in unit doses. As such the board has existing consultation requirements for patients leaving hospitals with discharge medication.

Mr. Partansky stated that the information the board will require on the poster should not be permitted to be printed alternatively on a receipt. Patients need this information before they purchase their prescription medications, not afterwards or when they return home. This information is needed while patients are in the pharmacy.

California law in Business and Professions Code section 4122 provides pharmacies with the option of printing the "Notice to Consumers" information on a receipt instead of posting the board's poster in the pharmacy. However, to encourage the display of the poster in pharmacies, the board has hired a graphic artist to design a poster that it is attractive and will be interesting to read. By so doing, the board hopes to maximize the number of pharmacies that post the poster in the pharmacy.

Referring to section 1707.2(f), Mr. Partansky stated that the board should restore the sentence that read: "If you have any questions regarding medications, please ask to speak with a pharmacist." He stated that he thought that this was a clearer message than the board's proposed new alternative: "Ask your pharmacist if you have additional questions."

The board believes that the key to an effective poster is to emphasize the five questions it wants patients to ask their pharmacists. The board also wants to stress the value of generics and that pharmacies must provide price quotations.

All other wording of the notice was edited to the bare minimum to permit the greatest emphasis on the on the questions. By so doing the board believes it will be able to assist consumers in learning more about their prescription medications, increase medication compliance with treatment regimens, reduce medication errors and generally increase patient well-being.

Mr. Partansky stated that the board needs to make certain that the state seal is printed on the poster so that the poster will look official and not appear as an advertisement.

The board will place a state seal on the poster as well as the board's logo which will provide credibility to the message on the poster as originating from a governmental agency and not another source.

Local Mandate:

None.

Business Impact:

The board has made a determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

Consideration of Alternatives:

The board has made has determined that no alternative presented would be more effective than or as effective as and less burdensome on affected private persons than the proposal described.